

APPLICANT(S): SALVI, Annibale et al.
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REMARKS

The present response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 1-14 are pending in the application. Claims 7-13 have been allowed. Claims 1-6 and 14 have been rejected. Claims 1 and 13-14 have been amended.

Applicants respectfully assert that the amendments to the claims add no new matter.

Applicants wish to thank the Examiner for allowing claims 7-13.

CLAIM REJECTIONS

35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 1-6 and 14 under 35 U.S.C. § 103(a), as being unpatentable over U.S Patent number 5,916,912 to Ames et al., (hereinafter the '912 Patent) and French Patent number 4,512M (hereinafter the '512 Patent) each taken alone or in view of U.S. Patent number 6,479,692 to Ekwuribe et al., (hereinafter the '692 Patent).

Applicants respectfully traverse the rejection of claims 1-6 and 14 under the '912 Patent and the '512 Patent, each alone or in combination with the '692 Patent.

Applicants assert that none of the '912 Patent, the '512 Patent, or the '692 Patent, alone or in combination, teach or suggest, "A salt of a thioctic acid with an L-carnitine zwitterion, said salt allowing simultaneous coadministration to a subject, ..." as claimed in Applicants' amended independent claim 1.

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The '912 Patent does not disclose carnitine as a zwitterion with thioctic acid for coadministration as disclosed in Applicants' amended claim 1, but instead a physiologically reactive sulphydryl group containing compounds glutathione, NAC and lipoic acid (col. 3, lines 1-2) as the active thiol compounds. Likewise, the '512 Patent does not teach or suggest "A salt of a thioctic acid with an L-carnitine zwitterion, said salt allowing simultaneous coadministration to a subject ..." as claimed in Applicants' amended independent claim 1, but rather the free acid form of carnitine.

Similarly, the '692 Patent does not teach or suggest the use of carnitine, any or other active pharmaceutical ingredient for that matter, as a zwitterion to stabilize the charge of a free acid, as required by Applicants' claim 1, as amended.

In addition, in the Office Action, the examiner alleges that the instant claims differ from '912 and '512 Patents in that the references disclose the free acid form of some the compounds whereas the instant claims are drawn to the alkaline metal, alkaline earth metal salts and quaternary ammonium of the compounds. The Examiner alleges that the '692 Patent discloses that salts such as alkaline metal salts, alkaline earth metal salts are salts that retain the desired biological activity of the parent compounds, therefore "there is ample motivation for one of ordinary skill in the art to modify the prior art compounds to arrive at the instantly claimed salts".

Applicants respectfully disagree. The '692 Patent does not teach or suggest the use of salt to balance a negative charge resulting from the combination of a positive end of a zwitterion with a free acid, as described in Applicants' amended claim 1, but instead, it discusses pharmaceutically acceptable salts of free acids in general.

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). Since none of the '912 Patent, the '512 Patent, or the '692 Patent, alone or in combination include all the elements of Applicants' claim 1, as amended, claim 1 is not made obvious by and is allowable over a combination of the '912 Patent and the '512 Patent and a combination of the '912 Patent and the '692 Patent.

Claims 2-6 and 14 depend from, directly or indirectly, claim 1, and therefore include all the limitations of amended claim 1. Therefore, Applicants respectfully assert that claims 2-6 and 14 are likewise allowable.

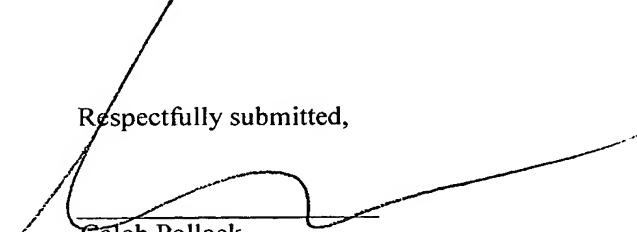
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Applicants respectfully request that the Examiner withdraw the rejection of claims 1-6 and 14 under the '912 Patent and the '512 Patent, each alone or in combination with the '692 Patent.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Except for the fees for the extension of time, being requested separately, no fees are believed to be due in connection with this paper. If any such fees are due, please charge such fees to deposit account No. 50-3355.

Respectfully submitted,

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Dated: May 19, 2006

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